WHAT IS CLAIMED IS:

- 1. A method of evaluating the efficiency of a sterilization process, which comprises the steps of:
- a) subjecting a sufficient amount of at least one prion protein degradation indicator in a container to said sterilization process; and
- b) determining the level of degradation of said indicator.
- 2. The method according to claim 1, wherein said indicator of step a) is transcribed by a gene naturally occurring in a fungus.
- 3. The method according to claim 2, wherein said fungus is selected from the group consisting of Saccharomyces cerevisiae, and Podospora anserina.
- 4. The method according to claim 3, wherein said indicator is transcribed by a gene selected from the group consisting of SUP35, URE2, and HET-s.
- 5. The method according to claim 2, wherein said indicator is selected from the group consisting of Sup35p, Ure2p, Het-s protein, and combination thereof.
- 6. The method according to claims 1 to 5, wherein said indicator is a purified form naturally occurring in Saccharomyces cerevisiae, Podospora anserina or a fungus, a recombinant form, an analog, a mutant, or a fragment of said indicator.

7. The method according to claim 1 to 5, wherein said indicator is a biological indicator, a biochemical indicator, or a chemical indicator.

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- 8. The method according to claim 1, wherein step b) is performed by determining the weight or the mass, quantifying radicals, colorimetric variations, radiometry, nephelometry, immuno-enzymatic method, Western blotting, dot blotting, radioimmuno assay, circular dichroism, electron microscopy, fluorescent microscopy, FTIR, Congo red binding, or proteinase digestion.
- 9. The method according to claim 1, wherein said sterilization process is performed by autoclaving, chemical exposure, dry heating, low temperature plasma gas, ozone-based exposure, or sterilization techniques using alkylant and/or oxidizing sterilizing agents.
- 10. The method according to claim 9, wherein said chemical exposure is a vapor or a solution selected from the group consisting of detergent, ethylene oxide, protease, sodium hydroxide, and enzyme.
- 11. The method of claim 1, wherein said amount of indicator of step a) is between 0.1 ng to 100 g.
- 12. The method of claim 1, wherein said container is of a material selected from the group consisting of paper, glass, borosilicate, metal, polymer, alloy, and composite.

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13. The method according to claim 11, wherein said container is porous, permeable, or semi-permeable.